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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,135	06/29/2006	Giampiero de Luca	SER-104	1670

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EXAMINER	
SNYDER, STUART	

ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
04/15/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/553,135	DE LUCA, GIAMPIERO	
	Examiner	Art Unit	
	STUART W. SNYDER	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 14-36 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In the Office Action mailed 7/30/2007, the Wands factors were used to determine whether or not the claimed method was enabled. The gist of the analysis is that there is currently no clinically proven effective method of treating SARS infection in humans. Post-filing non-Patent reviews reflect the Examiner's view of sparse clinical data (see, for example, Pyrc, *et al.*, Tai, and Haagmans and Osterhaus). Each recount the same few clinical studies and arrives at the same conclusion, that it is reasonable to study the use of Type I interferons, alone and in combination with other putative anti-SARS therapeutics, but to date there is no consensus for an effective treatment. Applicant's traverse the rejection by arguing that there is sufficient detail as to the type of interferon to use (IFN-β or IFN_{con}), the mode of administration, and dosage in the claims and specification to enable the method; *e.g.*, treatment of humans with SARS-CoV infection. Applicant further argues that the Examiner

failed to establish that effective methods of treating SARS-CoV infection are poorly defined.

Before considering Applicants argument, the Examiner notes that Applicants use the word "individual" as the subject of any claimed treatment; careful reading of the specification enlightens the reader of the meaning of word "individual" to be interchangeable with the word "human" and all previous and future arguments ascribe this meaning to the word individual.

The Examiner has cited three recent reviews related to SARS-CoV or coronavirus therapeutics. Haagmans and Osterhaus briefly mention several in vitro studies involving SARS-CoV treatment with Type I interferons, including the study of Cinatl, *et al.* previously cited by Applicants; similar in vitro studies using other animal and human coronaviruses also showed similar effects of IFNs. However, to date, the most relevant studies to the instantly claimed method are those of Haagmans, *et al.* (2004) and Loutfy, *et al.* (2003). In the former study, PEGylated IFN–α was used to ameliorate the effects of experimental infection of macaques whereas in the latter study, humans were treated with Ribavirin (monotherapy), IFN–α (monotherapy) and IFN–α in combination with corticosteroids—corticosteroids were the first therapeutic used against SARS to ameliorate symptoms of the infection in absence of a knowledge of the etiologic agent. Neither monotherapy regimen was found to be effective in ameliorating the morbidity or mortality of SARS-CoV infected humans, only high-dose corticosteroids in combination with IFN–α was substantially more effective no

treatment. Tai also recounts the Guangzhou study (see, Zhang, *et al.*, 2003) and concludes that only IFN-α plus high—dose corticosteroids were effective in reducing morbidity and mortality in human infected with SARS-CoV. Another uncontrolled study from Toronto is also recounted confirming that IFN-plus corticosteroids reduces morbidity and mortality associated with SARS-CoV infection of humans and appears to shorten the resolution of the infection and consequent pathology. Tai also reports the first prospective, placebo-controlled study of IFN-α treatment of human SARS-CoV infections. Finally, Stockman, *et al.* conducted a meta-analysis of many experimental SARS-CoV treatment studies and conclude that "Despite an extensive literature reporting on SARS treatments, it was not possible to determine whether treatments benefited patients during the SARS outbreak." Such studies included three *in vivo* studies using IFN for treatment of SARS in humans and determined that none were conclusive because of "lack of a consistent treatment regimen or suitable control group" and "a variety of treatments given masked the effect of IFN-α alone". Although IFN treatment of SARS-CoV in human appears to be a reasonable option, especially with IFN-β, the literature is silent regarding the efficacy of such treatment.

Therefore, even though Applicants claim a method for treatment of SARS-CoV infection in human that includes specific amounts, specific routes of administration, *etc.*, there is no indication from the available literature that *in vitro* and non-human models predict success for such methods in humans.

Rejection of claims 14-36 under 35 U.S.C. 112, 1st paragraph for lack of enablement is **maintained**.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Rejection of claims 14-36 under 35 U.S.C. 103(a) as being unpatentable over Higgins, *et al.* in view of Ksiazek, et al, Arnason, Weinstock-Guttman, *et al.*, Albrecht, and Chang, *et al.* is **withdrawn** in view of Applicants' agruments.

Conclusion

3. No claims are allowed.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to STUART W. SNYDER whose telephone number is (571)272-9945. The examiner can normally be reached on 9:00 AM-5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary E Mosher, Ph.D./
Primary Examiner, Art Unit 1648

Stuart W Snyder
Examiner
Art Unit 1648

sws